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₵ 02-19-19 8:19 AM ₵

S.B. 170
1st Sub. (Green)

Senator Evan J. Vickers proposes the following substitute bill:

PHARMACY AND PHARMACEUTICALS AMENDMENTS

2019 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Evan J. Vickers

House Sponsor: Brad M. Daw

LONG TITLE

General Description:

This bill amends provisions relating to the practice of pharmacy.

Highlighted Provisions:

This bill:

- amends the definition of "practice as a licensed pharmacy technician";
- adds a drug to the list of long-acting injectable drug therapies that can be administered by certain pharmacists;
- changes the requirements for certain supervising pharmacists;
- adds certain board certified urologists to the list of individuals who are qualified to be a dispensing medical practitioner; and
- reschedules certain drugs that are approved by the United States Food and Drug Administration and contain a component of cannabis.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

1st Sub. S.B. 170

58-17b-102, as last amended by Laws of Utah 2018, Chapter 295
58-17b-612, as last amended by Laws of Utah 2014, Chapter 72
58-17b-625, as enacted by Laws of Utah 2017, Chapter 384
58-17b-805, as enacted by Laws of Utah 2014, Chapter 72
58-37-4, as last amended by Laws of Utah 2018, Chapter 146

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-102** is amended to read:

58-17b-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Administering" means:

(a) the direct application of a prescription drug or device, whether by injection, inhalation, ingestion, or by any other means, to the body of a human patient or research subject by another person; or

(b) the placement by a veterinarian with the owner or caretaker of an animal or group of animals of a prescription drug for the purpose of injection, inhalation, ingestion, or any other means directed to the body of the animal by the owner or caretaker in accordance with written or verbal directions of the veterinarian.

(2) "Adulterated drug or device" means a drug or device considered adulterated under 21 U.S.C. Sec. 351 (2003).

(3) (a) "Analytical laboratory" means a facility in possession of prescription drugs for the purpose of analysis.

(b) "Analytical laboratory" does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are prediluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in vitro diagnostic use.

(4) "Animal euthanasia agency" means an agency performing euthanasia on animals by the use of prescription drugs.

(5) "Automated pharmacy systems" includes mechanical systems which perform

operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

(6) "Beyond use date" means the date determined by a pharmacist and placed on a prescription label at the time of dispensing that indicates to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(7) "Board of pharmacy" or "board" means the Utah State Board of Pharmacy created in Section 58-17b-201.

(8) "Branch pharmacy" means a pharmacy or other facility in a rural or medically underserved area, used for the storage and dispensing of prescription drugs, which is dependent upon, stocked by, and supervised by a pharmacist in another licensed pharmacy designated and approved by the division as the parent pharmacy.

(9) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

(10) "Class A pharmacy" means a pharmacy located in Utah that is authorized as a retail pharmacy to compound or dispense a drug or dispense a device to the public under a prescription order.

(11) "Class B pharmacy":

(a) means a pharmacy located in Utah:

(i) that is authorized to provide pharmaceutical care for patients in an institutional setting; and

(ii) whose primary purpose is to provide a physical environment for patients to obtain health care services; and

(b) (i) includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and

(ii) pharmaceutical administration and sterile product preparation facilities.

(12) "Class C pharmacy" means a pharmacy that engages in the manufacture, production, wholesale, or distribution of drugs or devices in Utah.

(13) "Class D pharmacy" means a nonresident pharmacy.

(14) "Class E pharmacy" means all other pharmacies.

(15) "Closed-door pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a specific entity, including a health maintenance organization or an infusion company, but not including a hospital pharmacy, a retailer of goods to the general public, or the office of a practitioner.

(16) "Collaborative pharmacy practice" means a practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain pharmaceutical care functions authorized by the practitioner or practitioners under certain specified conditions or limitations.

(17) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients and prevention of disease of human subjects.

(18) (a) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a limited quantity drug, sterile product, or device:

(i) as the result of a practitioner's prescription order or initiative based on the practitioner, patient, or pharmacist relationship in the course of professional practice;

(ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(b) "Compounding" does not include:

(i) the preparation of prescription drugs by a pharmacist or pharmacy intern for sale to another pharmacist or pharmaceutical facility;

(ii) the preparation by a pharmacist or pharmacy intern of any prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner; or

(iii) the preparation of a prescription drug, sterile product, or device which has been withdrawn from the market for safety reasons.

(19) "Confidential information" has the same meaning as "protected health

information" under the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

(20) "Controlled substance" means the same as that term is defined in Section 58-37-2.

(21) "Dietary supplement" has the same meaning as Public Law Title 103, Chapter 417, Sec. 3a(ff) which is incorporated by reference.

(22) "Dispense" means the interpretation, evaluation, and implementation of a prescription drug order or device or nonprescription drug or device under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient, research subject, or an animal.

(23) "Dispensing medical practitioner" means an individual who is:

(a) currently licensed as:

(i) a physician and surgeon under Chapter 67, Utah Medical Practice Act;

(ii) an osteopathic physician and surgeon under Chapter 68, Utah Osteopathic Medical Practice Act;

(iii) a physician assistant under Chapter 70a, Physician Assistant Act;

(iv) a nurse practitioner under Chapter 31b, Nurse Practice Act; or

(v) an optometrist under Chapter 16a, Utah Optometry Practice Act, if the optometrist is acting within the scope of practice for an optometrist; and

(b) licensed by the division under the Pharmacy Practice Act to engage in the practice of a dispensing medical practitioner.

(24) "Dispensing medical practitioner clinic pharmacy" means a closed-door pharmacy located within a licensed dispensing medical practitioner's place of practice.

(25) "Distribute" means to deliver a drug or device other than by administering or dispensing.

(26) (a) "Drug" means:

(i) a substance recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(ii) a substance that is required by any applicable federal or state law or rule to be dispensed by prescription only or is restricted to administration by practitioners only;

(iii) a substance other than food intended to affect the structure or any function of the body of humans or other animals; and

(iv) substances intended for use as a component of any substance specified in Subsections (26)(a)(i), (ii), (iii), and (iv).

(b) "Drug" does not include dietary supplements.

(27) "Drug regimen review" includes the following activities:

(a) evaluation of the prescription drug order and patient record for:

(i) known allergies;

(ii) rational therapy-contraindications;

(iii) reasonable dose and route of administration; and

(iv) reasonable directions for use;

(b) evaluation of the prescription drug order and patient record for duplication of therapy;

(c) evaluation of the prescription drug order and patient record for the following interactions:

(i) drug-drug;

(ii) drug-food;

(iii) drug-disease; and

(iv) adverse drug reactions; and

(d) evaluation of the prescription drug order and patient record for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(28) "Drug sample" means a prescription drug packaged in small quantities consistent with limited dosage therapy of the particular drug, which is marked "sample", is not intended to be sold, and is intended to be provided to practitioners for the immediate needs of patients for trial purposes or to provide the drug to the patient until a prescription can be filled by the patient.

(29) "Electronic signature" means a trusted, verifiable, and secure electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(30) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(31) "Hospital pharmacy" means a pharmacy providing pharmaceutical care to inpatients of a general acute hospital or specialty hospital licensed by the Department of Health under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.

(32) "Legend drug" has the same meaning as prescription drug.

(33) "Licensed pharmacy technician" means an individual licensed with the division, that may, under the supervision of a pharmacist, perform the activities involved in the technician practice of pharmacy.

(34) "Manufacturer" means a person or business physically located in Utah licensed to be engaged in the manufacturing of drugs or devices.

(35) (a) "Manufacturing" means:

(i) the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container; and

(ii) the promotion and marketing of such drugs or devices.

(b) "Manufacturing" includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(c) "Manufacturing" does not include the preparation or compounding of a drug by a pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation, compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical analysis.

(36) "Medical order" means a lawful order of a practitioner which may include a prescription drug order.

(37) "Medication profile" or "profile" means a record system maintained as to drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze the profile to provide pharmaceutical care.

(38) "Misbranded drug or device" means a drug or device considered misbranded under 21 U.S.C. Sec. 352 (2003).

(39) (a) "Nonprescription drug" means a drug which:

(i) may be sold without a prescription; and

(ii) is labeled for use by the consumer in accordance with federal law.

(b) "Nonprescription drug" includes homeopathic remedies.

(40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a person in Utah.

(41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

(42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located outside the state that is licensed and in good standing in another state, that:

(a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in this state pursuant to a lawfully issued prescription;

(b) provides information to a patient in this state on drugs or devices which may include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses; or

(c) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

(43) "Patient counseling" means the written and oral communication by the pharmacist or pharmacy intern of information, to the patient or caregiver, in order to ensure proper use of drugs, devices, and dietary supplements.

(44) "Pharmaceutical administration facility" means a facility, agency, or institution in which:

(a) prescription drugs or devices are held, stored, or are otherwise under the control of the facility or agency for administration to patients of that facility or agency;

(b) prescription drugs are dispensed to the facility or agency by a licensed pharmacist or pharmacy intern with whom the facility has established a prescription drug supervising relationship under which the pharmacist or pharmacy intern provides counseling to the facility or agency staff as required, and oversees drug control, accounting, and destruction; and

(c) prescription drugs are professionally administered in accordance with the order of a practitioner by an employee or agent of the facility or agency.

(45) (a) "Pharmaceutical care" means carrying out the following in collaboration with a prescribing practitioner, and in accordance with division rule:

(i) designing, implementing, and monitoring a therapeutic drug plan intended to achieve favorable outcomes related to a specific patient for the purpose of curing or preventing

the patient's disease;

(ii) eliminating or reducing a patient's symptoms; or

(iii) arresting or slowing a disease process.

(b) "Pharmaceutical care" does not include prescribing of drugs without consent of a prescribing practitioner.

(46) "Pharmaceutical facility" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into this state.

(47) (a) "Pharmaceutical wholesaler or distributor" means a pharmaceutical facility engaged in the business of wholesale vending or selling of a prescription drug or device to other than a consumer or user of the prescription drug or device that the pharmaceutical facility has not produced, manufactured, compounded, or dispensed.

(b) "Pharmaceutical wholesaler or distributor" does not include a pharmaceutical facility carrying out the following business activities:

(i) intracompany sales;

(ii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, if the activity is carried out between one or more of the following entities under common ownership or common administrative control, as defined by division rule:

(A) hospitals;

(B) pharmacies;

(C) chain pharmacy warehouses, as defined by division rule; or

(D) other health care entities, as defined by division rule;

(iii) the sale, purchase, or trade of a prescription drug or device, or an offer to sell, purchase, or trade a prescription drug or device, for emergency medical reasons, including supplying another pharmaceutical facility with a limited quantity of a drug, if:

(A) the facility is unable to obtain the drug through a normal distribution channel in sufficient time to eliminate the risk of harm to a patient that would result from a delay in obtaining the drug; and

(B) the quantity of the drug does not exceed an amount reasonably required for immediate dispensing to eliminate the risk of harm;

(iv) the distribution of a prescription drug or device as a sample by representatives of a manufacturer; and

(v) the distribution of prescription drugs, if:

(A) the facility's total distribution-related sales of prescription drugs does not exceed 5% of the facility's total prescription drug sales; and

(B) the distribution otherwise complies with 21 C.F.R. Sec. 1307.11.

(48) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.

(49) "Pharmacist-in-charge" means a pharmacist currently licensed in good standing who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of the pharmacy and all personnel.

(50) "Pharmacist preceptor" means a licensed pharmacist in good standing with one or more years of licensed experience. The preceptor serves as a teacher, example of professional conduct, and supervisor of interns in the professional practice of pharmacy.

(51) "Pharmacy" means any place where:

(a) drugs are dispensed;

(b) pharmaceutical care is provided;

(c) drugs are processed or handled for eventual use by a patient; or

(d) drugs are used for the purpose of analysis or research.

(52) "Pharmacy benefits manager or coordinator" means a person or entity that provides a pharmacy benefits management service as defined in Section 49-20-502 on behalf of a self-insured employer, insurance company, health maintenance organization, or other plan sponsor, as defined by rule.

(53) "Pharmacy intern" means an individual licensed by this state to engage in practice as a pharmacy intern.

(54) "Pharmacy technician training program" means an approved technician training program providing education for pharmacy technicians.

(55) (a) "Practice as a dispensing medical practitioner" means the practice of pharmacy, specifically relating to the dispensing of a prescription drug in accordance with Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, and

division rule adopted after consultation with the Board of pharmacy and the governing boards of the practitioners described in Subsection (23)(a).

(b) "Practice as a dispensing medical practitioner" does not include:

(i) using a vending type of dispenser as defined by the division by administrative rule; or

(ii) except as permitted by Section 58-17b-805, dispensing of a controlled substance as defined in Section 58-37-2.

(56) [~~(a)~~] "Practice as a licensed pharmacy technician" means engaging in practice as a pharmacy technician under the general supervision of a licensed pharmacist and in accordance with a scope of practice defined by division rule made in collaboration with the board.

[~~(b) "Practice as a licensed pharmacy technician" does not include:~~]

[~~(i) performing a drug utilization review, prescription drug order clarification from a prescriber, final review of the prescription, dispensing of the drug, or counseling a patient with respect to a prescription drug;~~]

[~~(ii) except as permitted by rules made by the division in consultation with the board, final review of a prescribed drug prepared for dispensing;~~]

[~~(iii) counseling regarding nonprescription drugs and dietary supplements unless delegated by the supervising pharmacist; or~~]

[~~(iv) receiving new prescription drug orders when communicating telephonically or electronically unless the original information is recorded so the pharmacist may review the prescription drug order as transmitted.~~]

(57) "Practice of pharmacy" includes the following:

(a) providing pharmaceutical care;

(b) collaborative pharmacy practice in accordance with a collaborative pharmacy practice agreement;

(c) compounding, packaging, labeling, dispensing, administering, and the coincident distribution of prescription drugs or devices, provided that the administration of a prescription drug or device is:

(i) pursuant to a lawful order of a practitioner when one is required by law; and

(ii) in accordance with written guidelines or protocols:

(A) established by the licensed facility in which the prescription drug or device is to be

administered on an inpatient basis; or

(B) approved by the division, in collaboration with the board and the Physicians Licensing Board, created in Section 58-67-201, if the prescription drug or device is to be administered on an outpatient basis solely by a licensed pharmacist;

(d) participating in drug utilization review;

(e) ensuring proper and safe storage of drugs and devices;

(f) maintaining records of drugs and devices in accordance with state and federal law and the standards and ethics of the profession;

(g) providing information on drugs or devices, which may include advice relating to therapeutic values, potential hazards, and uses;

(h) providing drug product equivalents;

(i) supervising pharmacist's supportive personnel, pharmacy interns, and pharmacy technicians;

(j) providing patient counseling, including adverse and therapeutic effects of drugs;

(k) providing emergency refills as defined by rule;

(l) telepharmacy;

(m) formulary management intervention; and

(n) prescribing and dispensing a self-administered hormonal contraceptive in accordance with Title 26, Chapter 64, Family Planning Access Act.

(58) "Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies.

(59) "Practice of telepharmacy across state lines" means the practice of pharmacy through the use of telecommunications and information technologies that occurs when the patient is physically located within one jurisdiction and the pharmacist is located in another jurisdiction.

(60) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

(61) "Prescribe" means to issue a prescription:

(a) orally or in writing; or

(b) by telephone, facsimile transmission, computer, or other electronic means of

communication as defined by division rule.

(62) "Prescription" means an order issued:

(a) by a licensed practitioner in the course of that practitioner's professional practice or by collaborative pharmacy practice agreement; and

(b) for a controlled substance or other prescription drug or device for use by a patient or an animal.

(63) "Prescription device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, and any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by or through a person or entity licensed under this chapter or exempt from licensure under this chapter.

(64) "Prescription drug" means a drug that is required by federal or state law or rule to be dispensed only by prescription or is restricted to administration only by practitioners.

(65) "Repackage":

(a) means changing the container, wrapper, or labeling to further the distribution of a prescription drug; and

(b) does not include:

(i) Subsection (65)(a) when completed by the pharmacist responsible for dispensing the product to a patient; or

(ii) changing or altering a label as necessary for a dispensing practitioner under Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, for dispensing a product to a patient.

(66) "Research using pharmaceuticals" means research:

(a) conducted in a research facility, as defined by division rule, that is associated with a university or college in the state accredited by the Northwest Commission on Colleges and Universities;

(b) requiring the use of a controlled substance, prescription drug, or prescription device;

(c) that uses the controlled substance, prescription drug, or prescription device in accordance with standard research protocols and techniques, including, if required, those approved by an institutional review committee; and

(d) that includes any documentation required for the conduct of the research and the handling of the controlled substance, prescription drug, or prescription device.

(67) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

(68) (a) "Self-administered hormonal contraceptive" means a self-administered hormonal contraceptive that is approved by the United States Food and Drug Administration to prevent pregnancy.

(b) "Self-administered hormonal contraceptive" includes an oral hormonal contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch.

(c) "Self-administered hormonal contraceptive" does not include any drug intended to induce an abortion, as that term is defined in Section 76-7-301.

(69) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

(70) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

(71) "Supportive personnel" means unlicensed individuals who:

(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed pharmacy technician in nonjudgmental duties not included in the definition of the practice of pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as those duties may be further defined by division rule adopted in collaboration with the board; and

(b) are supervised by a pharmacist in accordance with rules adopted by the division in collaboration with the board.

(72) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

(73) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

(74) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.

Section 2. Section **58-17b-612** is amended to read:

58-17b-612. Supervision -- Pharmacist-in-charge.

(1) (a) Any pharmacy, except a wholesaler, distributor, out-of-state mail service pharmacy, or class E pharmacy, shall be under the general supervision of at least one pharmacist licensed to practice in Utah. One pharmacist licensed in Utah shall be designated as the pharmacist-in-charge, whose responsibility it is to oversee the operation of the pharmacy.

(b) Notwithstanding Subsection 58-17b-102[~~(68)~~](70), a supervising pharmacist does not have to be in the pharmacy or care facility but shall be available via a telepharmacy system for immediate contact with the supervised pharmacy technician or pharmacy intern if:

(i) the pharmacy is located in[~~:~~] an area of need as defined by the division, in consultation with the board, by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act;

[~~(A) a remote rural hospital, as defined in Section 26-21-13.6; or~~]

[~~(B) a clinic located in a remote rural county with less than 20 people per square mile;~~]

(ii) the supervising pharmacist described in Subsection (1)(a) is not available; [~~and~~]

(iii) the telepharmacy system maintains records and files quarterly reports as required by division rule to assure that patient safety is not compromised[~~.~~]; and

(iv) the arrangement is approved by the division in collaboration with the board.

(c) Subsection (1)(b) applies to a pharmacy that is located in a hospital only if the hospital is controlled by a local board that owns no more than two hospitals; and

(d) A supervising pharmacist may not supervise more than two pharmacies simultaneously under Subsection (1)(b).

(2) Each out-of-state mail service pharmacy shall designate and identify to the division a pharmacist holding a current license in good standing issued by the state in which the pharmacy is located and who serves as the pharmacist-in-charge for all purposes under this chapter.

Section 3. Section **58-17b-625** is amended to read:

58-17b-625. Administration of a long-acting injectable drug therapy.

(1) A pharmacist may, in accordance with this section, administer a drug described in Subsection (2).

(2) Notwithstanding the provisions of Subsection 58-17b-102(57)(c)(ii)(B), the division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative

Rulemaking Act, establishing training for a pharmacist to administer the following long-acting injectables intramuscularly:

(a) aripiprazole;

(b) aripiprazole lauroxil;

[~~(b)~~] (c) paliperidone;

[~~(c)~~] (d) risperidone;

[~~(d)~~] (e) olanzapine;

[~~(e)~~] (f) naltrexone;

[~~(f)~~] (g) naloxone; and

[~~(g)~~] (h) drugs approved and regulated by the United States Food and Drug Administration for the treatment of the Human Immunodeficiency Virus.

(3) A pharmacist may not administer a drug listed under Subsection (2) unless the pharmacist:

(a) completes the training described in Subsection (2);

(b) administers the drug at a clinic or community pharmacy, as those terms are defined by the division, by administrative rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act; and

(c) is directed by the physician, as that term is defined in Section 58-67-102 or Section 58-68-102, who issues the prescription to administer the drug.

Section 4. Section **58-17b-805** is amended to read:

58-17b-805. Dispensing medical practitioner -- Cancer drug treatment regimen.

(1) For purposes of this section:

(a) "Cancer drug treatment regimen" means a prescription drug used to treat cancer, manage its symptoms, or provide continuity of care for a cancer patient.

(b) "Cancer drug treatment regimen" includes:

(i) a chemotherapy drug administered intravenously, orally, rectally, or by dermal methods; and

(ii) a drug used to support cancer treatment, including a drug used to treat, alleviate, or minimize physical and psychological symptoms or pain, to improve patient tolerance of cancer treatments, or to prepare a patient for a subsequent course of therapy.

(c) "Cancer drug treatment regimen" does not mean a drug listed under federal law as a

Schedule I, II, or III drug.

(2) An individual may be licensed as a dispensing medical practitioner with a scope of practice that permits the dispensing medical practitioner to prescribe and dispense a cancer drug treatment regimen if the individual:

(a) is licensed as described in Subsections 58-17b-102(23)(a)(i) and (ii); and

(b) is certified or eligible to be certified by:

(i) the American Board of Internal Medicine in medical oncology[.]; or

(ii) the American Board of Urology.

(3) A dispensing medical practitioner authorized to prescribe and dispense a cancer drug treatment regimen under this section may prescribe and dispense a cancer drug treatment regimen:

(a) to the practitioner's patient who is currently undergoing chemotherapy in an outpatient clinic setting; and

(b) if the practitioner determines that providing the cancer drug treatment regimen to the patient in the outpatient clinic setting is in the best interest of the patient or provides better access to care for the patient.

Section 5. Section **58-37-4** is amended to read:

58-37-4. Schedules of controlled substances -- Schedules I through V -- Findings required -- Specific substances included in schedules.

(1) There are established five schedules of controlled substances known as Schedules I, II, III, IV, and V which consist of substances listed in this section.

(2) Schedules I, II, III, IV, and V consist of the following drugs or other substances by the official name, common or usual name, chemical name, or brand name designated:

(a) Schedule I:

(i) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, when the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(A) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

(B) Acetyl fentanyl: (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide);

(C) Acetylmethadol;

(D) Acryl fentanyl (N-(1-Phenethylpiperidin-4-yl)-N-phenylacrylamide);

(E) Allylprodine;

(F) Alphacetylmethadol, except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM;

(G) Alphameprodine;

(H) Alphamethadol;

(I) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(J) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

(K) Benzylpiperazine;

(L) Benzethidine;

(M) Betacetylmethadol;

(N) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

(O) Beta-hydroxy-3-methylfentanyl, other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide;

(P) Betameprodine;

(Q) Betamethadol;

(R) Betaprodine;

(S) Butyryl fentanyl (N-(1-(2-phenylethyl)-4-piperidinyl)-N-phenylbutyramide);

(T) Clonitazene;

(U) Cyclopropyl fentanyl (N-(1-Phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

(V) Dextromoramide;

(W) Diampromide;

(X) Diethylthiambutene;

(Y) Difenoxin;

(Z) Dimenoxadol;

(AA) Dimepheptanol;

(BB) Dimethylthiambutene;

(CC) Dioxaphetyl butyrate;

(DD) Dipipanone;

(EE) Ethylmethylthiambutene;

(FF) Etizolam (1-Methyl-6-o-chlorophenyl-8-ethyl-4H-s-triazolo[3,4-c]thieno[2,3-e]1,4-diazepine);

(GG) Etonitazene;

(HH) Etoxeridine;

(II) Furanyl fentanyl (N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl] furan-2-carboxamide);

(JJ) Furethidine;

(KK) Hydroxypethidine;

(LL) Ketobemidone;

(MM) Levomoramide;

(NN) Levophenacylmorphan;

(OO) Methoxyacetyl fentanyl (2-Methoxy-N-(1-phenylethylpiperidinyl-4-yl)-N-acetamide);

(PP) Morpheridine;

(QQ) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

(RR) Noracymethadol;

(SS) Norlevorphanol;

(TT) Normethadone;

(UU) Norpipanone;

(VV) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4- piperidinyl] propanamide);

(WW) Para-fluoroisobutyryl fentanyl (N-(4-Fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

(XX) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

(YY) Phenadoxone;

(ZZ) Phenampromide;

(AAA) Phenomorphan;

(BBB) Phenoperidine;

(CCC) Piritramide;

(DDD) Proheptazine;

(EEE) Properidine;

(FFF) Propiram;

(GGG) Racemoramide;

(HHH) Tetrahydrofuran fentanyl (N-(1-Phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

(III) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]- propanamide;

(JJJ) Tilidine;

(KKK) Trimeperidine;

(LLL) 3-methylfentanyl, including the optical and geometric isomers (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]- N-phenylpropanamide);

(MMM) 3-methylthiofentanyl (N-[(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

(NNN) 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide also known as U-47700; and

(OOO) 4-cyano CUMYL-BUTINACA.

(ii) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(A) Acetorphine;

(B) Acetyldihydrocodeine;

(C) Benzylmorphine;

(D) Codeine methylbromide;

(E) Codeine-N-Oxide;

(F) Cyprenorphine;

(G) Desomorphine;

(H) Dihydromorphine;

(I) Drotebanol;

(J) Etorphine (except hydrochloride salt);

(K) Heroin;

(L) Hydromorphinol;

(M) Methyldesorphine;

(N) Methylhydromorphine;

(O) Morphine methylbromide;

(P) Morphine methylsulfonate;

(Q) Morphine-N-Oxide;

(R) Myrophine;

(S) Nicocodeine;

(T) Nicomorphine;

(U) Normorphine;

(V) Pholcodine; and

(W) Thebacon.

(iii) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation; as used in this Subsection (2)(a)(iii) only, "isomer" includes the optical, position, and geometric isomers:

(A) Alpha-ethyltryptamine, some trade or other names: etryptamine; Monase; α-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; α-ET; and AET;

(B) 4-bromo-2,5-dimethoxy-amphetamine, some trade or other names: 4-bromo-2,5-dimethoxy-α-methylphenethylamine; 4-bromo-2,5-DMA;

(C) 4-bromo-2,5-dimethoxyphenethylamine, some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; alpha-desmethyl DOB; 2C-B, Nexus;

(D) 2,5-dimethoxyamphetamine, some trade or other names: 2,5-dimethoxy-α-methylphenethylamine; 2,5-DMA;

(E) 2,5-dimethoxy-4-ethylamphetamine, some trade or other names: DOET;

(F) 4-methoxyamphetamine, some trade or other names: 4-methoxy-α-methylphenethylamine; paramethoxyamphetamine, PMA;

(G) 5-methoxy-3,4-methylenedioxyamphetamine;

(H) 4-methyl-2,5-dimethoxy-amphetamine, some trade and other names: 4-methyl-2,5-dimethoxy-α-methylphenethylamine; "DOM"; and "STP";

(I) 3,4-methylenedioxy amphetamine;

(J) 3,4-methylenedioxymethamphetamine (MDMA);

(K) 3,4-methylenedioxy-N-ethylamphetamine, also known as N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA;

(L) N-hydroxy-3,4-methylenedioxyamphetamine, also known as N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA;

(M) 3,4,5-trimethoxy amphetamine;

(N) Bufotenine, some trade and other names: 3-(β-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;

(O) Diethyltryptamine, some trade and other names: N,N-Diethyltryptamine; DET;

(P) Dimethyltryptamine, some trade or other names: DMT;

(Q) Ibogaine, some trade and other names: 7-Ethyl-6,6β,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1', 2':1,2] azepino [5,4-b] indole; Tabernanthe iboga;

(R) Lysergic acid diethylamide;

(S) Marijuana;

(T) Mescaline;

(U) Parahexyl, some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl;

(V) Peyote, meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts (Interprets 21 USC 812(c), Schedule I(c) (12));

(W) N-ethyl-3-piperidyl benzilate;

(X) N-methyl-3-piperidyl benzilate;

(Y) Psilocybin;

(Z) Psilocyn;

(AA) Tetrahydrocannabinols, naturally contained in a plant of the genus Cannabis

(cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following: Δ1 cis or trans tetrahydrocannabinol, and their optical isomers Δ6 cis or trans tetrahydrocannabinol, and their optical isomers Δ3,4 cis or trans tetrahydrocannabinol, and its optical isomers, and since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered;

(BB) Ethylamine analog of phencyclidine, some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE;

(CC) Pyrrolidine analog of phencyclidine, some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP;

(DD) Thiophene analog of phencyclidine, some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP; and

(EE) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine, some other names: TCPy.

(iv) Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(A) Mecloqualone; and

(B) Methaqualone.

(v) Any material, compound, mixture, or preparation containing any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers, and salts of isomers:

(A) Aminorex, some other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenyl-2-oxazolamine;

(B) Cathinone, some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone;

(C) Fenethylline;

(D) Methcathinone, some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR1432, its salts, optical isomers, and salts of optical isomers;

(E) (±)cis-4-methylaminorex ((±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

(F) N-ethylamphetamine; and

(G) N,N-dimethylamphetamine, also known as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine.

(vi) Any material, compound, mixture, or preparation which contains any quantity of the following substances, including their optical isomers, salts, and salts of isomers, subject to temporary emergency scheduling:

(A) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl); and

(B) N-[1- (2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl).

(vii) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of gamma hydroxy butyrate (gamma hydrobutyric acid), including its salts, isomers, and salts of isomers.

(b) Schedule II:

(i) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including:

(I) Raw opium;

(II) Opium extracts;

(III) Opium fluid;

(IV) Powdered opium;

(V) Granulated opium;

(VI) Tincture of opium;

(VII) Codeine;

(VIII) Ethylmorphine;

(IX) Etorphine hydrochloride;

(X) Hydrocodone;

(XI) Hydromorphone;

(XII) Metopon;

(XIII) Morphine;

(XIV) Oxycodone;

(XV) Oxymorphone; and

(XVI) Thebaine;

(B) Any salt, compound, derivative, or preparation which is chemically equivalent or identical with any of the substances referred to in Subsection (2)(b)(i)(A), except that these substances may not include the isoquinoline alkaloids of opium;

(C) Opium poppy and poppy straw;

(D) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation which is chemically equivalent or identical with any of these substances, and includes cocaine and ecgonine, their salts, isomers, derivatives, and salts of isomers and derivatives, whether derived from the coca plant or synthetically produced, except the substances may not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; and

(E) Concentrate of poppy straw, which means the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy.

(ii) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, when the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation, except dextrorphan and levopropoxyphene:

(A) Alfentanil;

(B) Alphaprodine;

(C) Anileridine;

(D) Bezitramide;

(E) Bulk dextropropoxyphene (nondosage forms);

(F) Carfentanil;

(G) Dihydrocodeine;

(H) Diphenoxylate;

(I) Fentanyl;

(J) Isomethadone;

(K) Levo-alphacetylmethadol, some other names: levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM;

(L) Levomethorphan;

(M) Levorphanol;

(N) Metazocine;

(O) Methadone;

(P) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

(Q) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;

(R) Pethidine (meperidine);

(S) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;

(T) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;

(U) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(V) Phenazocine;

(W) Piminodine;

(X) Racemethorphan;

(Y) Racemorphan;

(Z) Remifentanil; and

(AA) Sufentanil.

(iii) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(A) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(B) Methamphetamine, its salts, isomers, and salts of its isomers;

(C) Phenmetrazine and its salts; and

(D) Methylphenidate.

(iv) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(A) Amobarbital;

(B) Glutethimide;

(C) Pentobarbital;

(D) Phencyclidine;

(E) Phencyclidine immediate precursors: 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile (PCC); and

(F) Secobarbital.

(v) (A) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of Phenylacetone.

(B) Some of these substances may be known by trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; and methyl benzyl ketone.

(vi) Nabilone, another name for nabilone: (±)-trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo[b,d]pyran-9-one.

(vii) Ŝ→ **[~~Any component of marijuana in a~~] A** ←Ŝ drug product Ŝ→ **or preparation** ←Ŝ that Ŝ→ **contains any component of marijuana, including tetrahydrocannabinol, and** ←Ŝ is approved by the United States Food and Drug Administration and scheduled by the Drug Enforcement Administration in Schedule II of the federal Controlled Substances Act, Title II, P.L. 91-513.

(c) Schedule III:

(i) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers whether optical, position, or geometric, and salts of the isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(A) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II, which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under Section 1308.32 of Title 21 of the

Code of Federal Regulations, and any other drug of the quantitive composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances;

(B) Benzphetamine;

(C) Chlorphentermine;

(D) Clortermine; and

(E) Phendimetrazine.

(ii) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(A) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or any salt of any of them, and one or more other active medicinal ingredients which are not listed in any schedule;

(B) Any suppository dosage form containing amobarbital, secobarbital, or pentobarbital, or any salt of any of these drugs which is approved by the Food and Drug Administration for marketing only as a suppository;

(C) Any substance which contains any quantity of a derivative of barbituric acid or any salt of any of them;

(D) Chlorhexadol;

(E) Buprenorphine;

(F) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under the federal Food, Drug, and Cosmetic Act, Section 505;

(G) Ketamine, its salts, isomers, and salts of isomers, some other names for ketamine: ± -2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone;

(H) Lysergic acid;

(I) Lysergic acid amide;

(J) Methyprylon;

(K) Sulfondiethylmethane;

(L) Sulfonethylmethane;

(M) Sulfonmethane; and

(N) Tiletamine and zolazepam or any of their salts, some trade or other names for a tiletamine-zolazepam combination product: Telazol, some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone, some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e] [1,4]-diazepin-7(1H)-one, flupyrazapon.

(iii) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product, some other names for dronabinol: (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.

(iv) Nalorphine.

(v) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid:

(A) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(B) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active non-narcotic ingredients in recognized therapeutic amounts;

(C) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

(D) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts;

(E) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active non-narcotic ingredients in recognized therapeutic amounts;

(F) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts;

(G) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts; and

(H) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(vi) Unless specifically excepted or unless listed in another schedule, anabolic steroids including any of the following or any isomer, ester, salt, or derivative of the following that promotes muscle growth:

(A) Boldenone;

(B) Chlorotestosterone (4-chlortestosterone);

(C) Clostebol;

(D) Dehydrochlormethyltestosterone;

(E) Dihydrotestosterone (4-dihydrotestosterone);

(F) Drostanolone;

(G) Ethylestrenol;

(H) Fluoxymesterone;

(I) Formebulone (formebolone);

(J) Mesterolone;

(K) Methandienone;

(L) Methandranone;

(M) Methandriol;

(N) Methandrostenolone;

(O) Methenolone;

(P) Methyltestosterone;

(Q) Mibolerone;

(R) Nandrolone;

(S) Norethandrolone;

(T) Oxandrolone;

(U) Oxymesterone;

(V) Oxymetholone;

(W) Stanolone;

(X) Stanozolol;

(Y) Testolactone;

(Z) Testosterone; and

(AA) Trenbolone.

(vii) Anabolic steroids expressly intended for administration through implants to cattle or other nonhuman species, and approved by the Secretary of Health and Human Services for use, may not be classified as a controlled substance.

(viii) Ŝ→ **[~~Any component of marijuana in a~~]** **A** ←Ŝ drug product Ŝ→ **or preparation** ←Ŝ that Ŝ→ **contains any component of marijuana, including tetrahydrocannabinol, and** ←Ŝ is approved by the United States Food and Drug Administration and scheduled by the Drug Enforcement Administration in Schedule III of the federal Controlled Substances Act, Title II, P.L. 91-513.

(d) Schedule IV:

(i) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit, or any salts of any of them.

(ii) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(A) Alprazolam;

(B) Barbital;

(C) Bromazepam;

(D) Butorphanol;

(E) Camazepam;

(F) Carisoprodol;

(G) Chloral betaine;

(H) Chloral hydrate;

(I) Chlordiazepoxide;

(J) Clobazam;

(K) Clonazepam;

(L) Clorazepate;

(M) Clotiazepam;

(N) Cloxazolam;

(O) Delorazepam;

(P) Diazepam;

(Q) Dichloralphenazone;

(R) Estazolam;

(S) Ethchlorvynol;

(T) Ethinamate;

(U) Ethyl loflazepate;

(V) Fludiazepam;

(W) Flunitrazepam;

(X) Flurazepam;

(Y) Halazepam;

(Z) Haloxazolam;

(AA) Ketazolam;

(BB) Loprazolam;

(CC) Lorazepam;

(DD) Lormetazepam;

(EE) Mebutamate;

(FF) Medazepam;

(GG) Meprobamate;

(HH) Methohexital;

(II) Methylphenobarbital (mephobarbital);

(JJ) Midazolam;

(KK) Nimetazepam;

(LL) Nitrazepam;

(MM) Nordiazepam;

(NN) Oxazepam;

(OO) Oxazolam;

(PP) Paraldehyde;

(QQ) Pentazocine;

(RR) Petrichloral;

(SS) Phenobarbital;

(TT) Pinazepam;

(UU) Prazepam;

(VV) Quazepam;

(WW) Temazepam;

(XX) Tetrazepam;

(YY) Triazolam;

(ZZ) Zaleplon; and

(AAA) Zolpidem.

(iii) Any material, compound, mixture, or preparation of fenfluramine which contains any quantity of the following substances, including its salts, isomers whether optical, position, or geometric, and salts of the isomers when the existence of the salts, isomers, and salts of isomers is possible.

(iv) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers whether optical, position, or geometric isomers, and salts of the isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(A) Cathine ((+)-norpseudoephedrine);

(B) Diethylpropion;

(C) Fencamfamine;

(D) Fenproprex;

(E) Mazindol;

(F) Mefenorex;

(G) Modafinil;

(H) Pemoline, including organometallic complexes and chelates thereof;

(I) Phentermine;

(J) Pipradrol;

(K) Sibutramine; and

(L) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(v) Unless specifically excepted or unless listed in another schedule, any material,

compound, mixture, or preparation which contains any quantity of dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane), including its salts.

(vi) Ŝ→ **[~~Any component of marijuana in a~~]** **A** ←Ŝ drug product Ŝ→ **or preparation** ←Ŝ that Ŝ→ **contains any component of marijuana and** ←Ŝ is approved by the United States Food and Drug Administration and scheduled by the Drug Enforcement Administration in Schedule IV of the federal Controlled Substances Act, Title II, P.L. 91-513.

(e) Schedule V:

(i) Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, which includes one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(A) not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(B) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(C) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(D) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(E) not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(F) not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit;

(G) unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains Pyrovalerone having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers; and

(H) all forms of Tramadol.

(ii) [~~Cannabidiol~~] Ŝ→ **[~~Any component of marijuana, including cannabidiol, in a~~]** **A** ←Ŝ drug product Ŝ→ **or preparation** ←Ŝ that Ŝ→ **contains any component of marijuana, including cannabidiol, and** ←Ŝ is approved by the United States Food and Drug Administration and scheduled by the Drug Enforcement Administration in Schedule V of the federal Controlled Substances Act, Title II, P.L. 91-513.